



# DEPARTMENT OF COMMERCE **Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR			ATTORNEY DOCKET NO.
09/380,546	11/29/99	WALLACH		D	WALLACH=23
		HM12/1109	コ	EXAMINER	
BROWDY & NEIMARK 419 SEVENTH STREET NW		10112/1107		WHITEMAN, B	
				ART UNIT	PAPER NUMBER
WASHINGTON 1	DC 20004			1633	. 17
				J	11/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

		Application No.	Applicant(s)				
Office Action Summary							
		09/380,546 Examiner	WALLACH ET AL.				
		Brian Whiteman	Art Unit				
	The MAILING DATE of this communication app						
Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status	Decree in the communication ( ) (i)						
	Responsive to communication(s) filed on <u>04 C</u>						
	, <del>_</del>	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 44-62 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>44-62</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
Certified copies of the priority documents have been received in Application No							
Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
2) Notice	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ition Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5.1</u>	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)				
I.S. Patent and Trad	emark Office						

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#### **DETAILED ACTION**

### **Non-Final Rejection**

The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be to directed to Brian Whiteman, Art Unit 1633.

## **Priority**

Priority to PCT/IL98/00098 filed on 2/26/98 is acknowledged.

### Information Disclosure Statement

The information disclosure statement filed on February 29, 2000 does not fully comply with the requirements of 37 CFR 1.98 because: applicants do not properly cite the journal article(s) listed on the 1449. The listing of the page nos. of journal article (AI) is missing.

The information disclosure statement filed on September 17, 2001 does not fully comply with the requirements of 37 CFR 1.98 because: applicants do not properly cite the journal article(s) listed on the 1449. The date of the foreign patent (AP) is incorrect.

The examiner has considered all of the references, but in order to have the journal article (AI) and the foreign patent (AP) initialed and dated on the 1449, a new 1449 properly citing the journal article and the foreign patent must be filed with the response to this office action. Failure to comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the non-complying information **not** being considered. See 37 CFR 1.97(i).

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Applicant's election with traverse of Group I, claims 1-10, 14 and 16-18, in (paper no. 13) is acknowledged. In addition, applicants' election of species G1α isoform encompassing SEQ ID NOs: 1 and 2 is also acknowledged (paper no. 13, page 8).

Acknowledgement is made of applicants' deletion of claims 1-43 and addition of claims 44-62 in paper no. 13 filed on 9/20/01. Applicants state, "Claims with the subject matter of Group I (claims 1-10, 14, 16-18) and Group II (claims 11-13, 16-18, 20, 26, 28-29, 32-36) remain in the case, and the restriction requirement, insofar as it seeks to restrict the DNA from the polypeptide which it encodes, is respectively traversed." (see paper no. 13, page 6)

The traversal is on the ground(s) that 1) The protein and the DNA exhibit corresponding special technical feature (page AI-43, Example 17 in Part 2 of Annex B of the PCT Administrative Instructions). 2) Group I and II should be examined in this case. 3) The G1 $\alpha$  and the G1 $\beta$  isoforms are clearly structurally related, as shown in Figure 3, the two sequences are identical in the first 222 amino acid residues and there is not reason to believe that they are different functionally with regard to their site of action. See paper no. 13 pages 6-8.

The applicants' traversal encompassing issues 1-3 is found partially persuasive because of Example 17 in Part 2 of Annex B of the PCT Administrative Instructions. However, PCT guideline, 37 CFR 1.475(d), states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

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In view of the guideline, the application is allowed one product, one method of making the product, and one method of using the product. However, new claims 60-62 encompass DNA therapy and protein therapy that were in separate groups in restriction paper no. 11, pages 2 and 3 following the PCT guidelines. Therefore, claims directed to protein therapy are considered non-elected because they are directed to a second method of using the claimed product.

The traversal is found partially persuasive and claims encompassing SEQ ID NOs: 3 and 4 are rejoined with the elected invention, however claims 60-62 encompassing polypeptide therapy are considered non-elected.

Claims 60-62 (encompassing polypeptide therapy) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made with traverse in Paper No. 13.

Elected claims 44-62 (encompassing SEQ ID NO: 1, 2, 3, 4 and DNA therapy), to which the following grounds of rejection are applicable, are pending examination.

Claims 60-62 are objected because the claims are dependent on a non-elected invention.

Applicant is required to amend the claim(s).

Claims 60-62 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 60-62 should be amended to reflect the elected invention of Group I. Should applicant amend the claims, so that the claims no longer resemble the elected invention, another restriction may be necessary.

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## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) A DNA sequence comprising either SEQ ID NO: 1 or 3 and fragment thereof; or comprising the amino acid set forth in either SEQ ID NO: 2 or 4, which sequences are capable of binding to either MORT-1 and/or MACH proteins; 2) A vector comprising the DNA of 1; 3) A host cell containing the vector of 2; 4) A method for producing a polypeptide set forth in either SEQ ID NO: 2 or 4; 5) A polypeptide sequence which is capable of binding to either MORT-1 and/or MACH proteins, wherein said sequence comprises the amino acid sequence of SEQ ID NO: 2 or 4 and does not reasonably provide enablement for the rest of the disclosed embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in <u>In re Wands</u>, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

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For clarification purposes G1 $\alpha$  is also known as CASH $\alpha$  and G1 $\beta$  is also known as CASH $\beta$ .

The disclosure claims a molecule comprising a DNA sequence encoding a polypeptide and/or a polypeptide which is capable of binding to one or more of MORT-1, Mch4, and MACH proteins, which polypeptide has the amino acid sequence of a fragment of a G1 protein isoform whose sequence is that of SEQ ID NO: 2 (CASHα) or 4 (CASHβ); an analog or a derivative of a G1 protein isoform whose sequence is that of SEQ ID NO: 2 or 4, which differs from the SEQ ID NO: 2 or 4 by no more than then substitutions, deletions, and/or insertions of amino acid residues and is capable of binding to one or more of MORT-1, Mch4, and MACH proteins. In view of the state of the art and the as-filed specification, it is not apparent to one skilled in the art if any analog or derivative of a G1 protein with a nucleic acid encoding the polypeptide set forth in SEQ ID NO: 2 or 4, would possess the same biological activity compared to the polypeptide set forth in SEQ ID NO: 2 or 4. Since, the relationship between a sequence of a peptide and its tertiary structure (i.e. its activity) is not well understood and is not predictable (e.g. see Chiu et al., Folding and Design, 1998, pp. 23-228), it would required undue experimentation for one skilled in the art to arrive at other peptides that have either CASHB or CASHB activity. In addition, in Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPO2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 U.S.C. 112, first paragraph, if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for the determination of other genetic

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sequences that are embraced by the claim. This is the case here. In other words, since it would require undue experimentation to identify other peptides that have CASH activity, it certainty would require undue experimentation to make their corresponding DNA and, therefore any other nucleotide sequence other than the sequence encoded by either SEQ ID NO: 1 or 3 or the DNA encoding either the polypeptide set forth in SEQ ID NO: 2 or 4, is not enabled by the specification.

Furthermore with respect to claims 44-48 and 54-58 encompassing either a DNA sequence encoding a polypeptide or a polypeptide which is capable of binding to one or more of MORT-1, Mch4, and MACH and affects the intracellular signaling process initiated by the binding of FAS ligand to FAS-R or the binding of TNF to p55-R, the specification is not enabled for either a DNA sequence (SEQ ID NO; 1 and 3) encoding a polypeptide or a polypeptide (SEQ ID NO: 2 and 4) which is capable of binding to Mch4 and that affect the intracellular signaling process. Goltsev et al., The Journal of Biological Chemistry, Vol. 272. 1997, pages 19643-19644 (Applicants' IDS), display that in a two-hybrid testing of the interactive properties of CASHα and CASHβ reveal that both variants interact with MORT1/FADD and CASP-8 (MACH). However, Goltsev displays that through two-hybrid screening for proteins that bind to CASP-10 (Mch4), CASHα did not bind to CASP-10 at all and CASHβ was found to bind weakly to CASP10 (page 19643).

In addition, the as-filed specification examined CASHα in either HeLa cells (a cancer cell line) or 293 cells (an immortalized human cell line) and its effect on p55R or a chimeric receptor comprised of p55R and FAS R by over-expressing CASHα (page 96). Expression of the CASHα affected the two cell lines very differently (page 96). In the 293 cells, expression

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resulted in marked cytotoxicity. In HeLa cells it inhibited cytotoxicity of p55-R and FAS-R. Also, the as-filed specification states, "The G1 proteins (CASH\u03c3) and its isoforms are suspected to be expressed in different tissues at markedly different levels and apparently with different patterns of isotypes as indicated in co-owned co-pending pending applications (page 56). In addition, with respect to experiments over-expressing CASHα, Goltsev states, "part of the effects observed when expressing a protein in amounts far higher than its normal level will turn out to be unrelated to its real function (page 19644)." In view of the unpredictability of the two novel proteins and the lack of sufficient guidance provided by the specification for displaying the biological function of each novel protein since over-expressing a protein usually results in an unrelated function and the specification has not provided sufficient guidance to circumvent this area of concern expressed by Goltsev, it would require an undue amount of experimentation to determine how either CASHa or CASHB would sufficiently bind to Mch4 or affect any intracellularly pathway. Furthermore, in view of the varied expression of CASHα in two different cell lines, it would take one skilled in the art an undue amount of experimentation to reasonably correlate the biological effect of CASHα expression when CASHα is transfected into a cell because the expression of CASHa could result in cytotoxicity or inhibition of cytotoxicity. Also, in view of the In re Wands Factors, listed above, the specification lacks sufficient description for the unpredictability of the biological activity of CASHB because the specification fails to provide a representative number of cell lines (e.g. non-cancerous or nonimmortalized cell line) that display the same function of CASHB when transfected into HeLa or 293 cells, which are abnormal cell lines. Thus, it would take one skilled in the art an undue amount of experimentation to determine how to use CASHB to affect the intracellular signaling

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process initiated by the binding of FAS ligand to FAS-R or the binding of TNF to p55-R in a normal cell line.

Furthermore, and with respect to claims 60-62 that are directed to a method for the modulation of cell death or inflammatory processes, one skilled in the art would determine that these claims are directed to gene therapy comprising the modulation of cell death or inflammatory processes in a mammal and directed to any therapeutic treatment of a mammal; the state of the art in 1998, exemplified Anderson et al., *Nature*, Vol. 392, pp. 25-30, April 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

- 1) The type of vector and amount of DNA constructs to be administered,
- 2) The route and time course of administration, the sites of administration, and successful uptake of the claimed DNA at the target site;
- 3) The trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA product, the amount and stability of the protein produced, and
- 4) What amount of the expressed proteins considered to be therapeutically effective for a DNA therapy method (Anderson, *Nature*, Vol. 392, pp. 25-30, April 1998).

In addition, all of these issues differ dramatically based on the specific vector used, the route of administration, the animal being treated, therapeutically effective amount of the DNA, and the disease being treated.

Anderson indicates that the state of the art before 1998, and teaches that gene therapy is a powerful new technology that still requires several years before it will make a noticeable impact

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on the treatment of disease, and that several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered (pp. 25-30).

Anderson further teaches that the reason for the low efficiency of gene transfer and expression in human patients is that we still lack the basis understanding of how vectors should be constructed what regulatory sequences are appropriated for which cell types (page 30, column 1, last paragraph). Furthermore, Verma, *Nature*, Vol. 389, pages 239-242, 1997, indicates that factors including the nature of the diseases and/or disorders, the nature of a DNA and/or target tissue, and a delivery system and/or amounts of the DNA complexes employed in the delivery system that would generate a therapeutic effect *in vivo* must be considered for any gene therapy method to be successful (page 238, columns 1 and 2). Thus, gene therapy is considered unpredictable.

The as-filed specification cites a patent (US Patent No. 5,108,921) that reviews available methods for transmembrane delivery of molecules by receptor mediated endocytosis. (page 47). In view of the doubts expressed by Anderson and Verma, the experiments listed above, and the references cited in the specification, the specification does not reasonably enable one skilled in the art to determine how to use SEQ ID NO: 1 or 3 or a DNA encoding SEQ ID NO: 2 or 4 in a method for modulating cell death or inflammatory processes. The as-filed specification displays inhibition or stimulation of the apoptosis process by transfecting either CASHα or CASHβ in two cancerous cell lines. The US Patent No. 5,108,921 and the specification do not address the concerns set forth by Anderson and Verma because one skilled in the art would not be able to reasonably extrapolate due to the lack of sufficient guidance provided by the specification for what type of cell is being is targeting, the mode of action (whether the process is being inhibited

or stimulated), and the amount of protein required to modulate a cell. Furthermore, the as-filed specification fails to provide sufficient description of whether CASHα or CASHβ directly or indirectly modulate the cell death or inflammatory process in cells. Furthermore, one skilled in the art of gene therapy cannot reasonably correlate results in vitro results using either an immortalized cell line or a cancerous cell line to any method of modulating cell death or an inflammatory process for a therapeutic response in any cell line without an undue amount of experimentation. Thus, since the physiological role of CASHα or CASHβ is uncertain (Goltsev et al., page 19644) or not defined due to the lack of working examples, the disclosure is not enabled for any method of modulating cell death or inflammatory process in a mammal using DNA (SEQ ID NOs: 1 or 3) or DNA encoding SEQ ID NOs: 2 or 4 in the form of a vector.

As a result, it is not apparent how one skilled in the art determines, without undue experimentation, which of the claimed vectors carrying SEQ ID NOs: 1 or 3 or DNA encoding SEQ ID NOs: 2 or 4 generate a therapeutic effect, how is it apparent as to how one skilled in the art, without any undue experimentation, practices any nucleic acid therapy method as contemplated by the claims, particularly given the unpredictability of nucleic acid therapy as a whole and/or the doubts expressed in the art of record.

At best the application is enabled 1) A DNA sequence encoding either SEQ ID NO: 1 or 3; or the amino acid set forth in either SEQ ID NO: 2 or 4, which is capable of binding to either MORT-1 or MACH proteins; 2) A vector comprising the DNA of 1; 3) A host cell containing the vector of 2; 4) A method for producing the polypeptide set forth in either SEQ ID NO: 2 or 4; 5) A polypeptide which is capable of binding to either MORT-1 or MACH proteins, which polypeptide has the amino acid sequence of SEQ ID NO: 2 or 4.

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In conclusion, the as-filed specification and claims coupled with the state of the art at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable the claimed invention 1-5 listed above. Given that gene therapy wherein any carrier is employed to correct a disease or a medical condition in any mammal was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to a gene therapy effect produced by any of the gene delivery vectors cited in the claims, one skilled in the art would have to engage in a large quantity of experimentation in order to practice the claimed invention based on the applicant's disclosure and the unpredictability of gene therapy. In addition, the lack of guidance for making and/or using any amino acid contemplated by the claims does not reasonably extrapolate to the full scope of the claimed invention encompassing any unknown DNA molecule encoding a mutated polypeptide of SEQ ID NOs: 2 and 4 or the amino acid sequences set forth in SEQ ID NOs: 2 and 4. Furthermore, the disclosure does not provide sufficient guidance in view of Chiu et al., Folding and Design, 1998, pp. 23-228 and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991) for making and/or using unknown DNA sequences encoding an analog or derivative of the polypeptide set forth in SEQ ID NOs: 2 or 4.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 45-52, 55-59, and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The statement in claims 45-49, "A molecule in accordance with claim 44" is indefinite because it does not point out what molecule a molecule in accordance with claim 44 is referring to in the claim. The dependent claims should state "The molecule in accordance with claim 44".

The statement in claims 50, 51, 52, "A vector comprising a molecule in accordance with claim 44" is indefinite because it does not point out what molecule a vector in accordance with claim 49 is referring to in the claim. The dependent claims should state "The vector in accordance with claim 49".

The statement in claims 55-59, "A polypeptide in accordance with claim 54" is indefinite because it does not point out what a polypeptide a polypeptide in accordance with claim 54 is referring to in the claim. The dependent claims should state "The polypeptide in accordance with claim 54".

The statement in claim 62, "A method according to claim 60" is indefinite because it does not point out which method a method according to claim 60 is referring to in the claim. The dependent claims should state "The method according to claim 60".

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 44(a,b,c), 49, 50, 51, 52, 53, and 54(b,c) are rejected under 35 U.S.C. 102(e) as being anticipated by Sul et al. (US Patent NO. 6,242,569, file date 2/5/97). Sul claims an

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isolated Casper protein comprising SEQ ID NO: 2 or a fragment thereof comprising SEQ ID NO: 2, residues 1-96, 1-202, 1-435, 78-480, 192-435, 192-480, 390-480 or residue, 360 joined directly to at least 6 residues of SEQ ID NO: 2 flanking residue 360, wherein said protein specifically binds at least one of a FADD, TRAF1, TRAF2, Caspase-3, or Caspase-8 protein (column 19, claim 2). The DNA sequence encoding the amino acid sequence claimed by Sul is 99.8% identical to the applicants' claimed DNA sequence encoding SEQ ID NO: 2 and 100% identical to the applicants' claimed DNA sequence encoding SEQ ID NO: 4. In addition, the amino acid sequence claimed by Sul is 99.8% identical to applicants' SEQ ID NO: 2. Also, the amino acid claimed by Sul is 91% identical to applicants' amino acid SEQ ID NO: 4, but has 12 different amino acids and does not read on claim 44c or claim 54c, however, the amino acid claimed by Sul reads on claims 44b and 54b. In addition, the DNA sequence claimed by Sul is 87% identical to applicants' SEQ ID NO: 1 and 74.7% identical to SEQ ID NO: 3. Furthermore, the Caspase-8 protein is also known as the MACH protein. Sul also teaches that the proteins may be produced recombinantly from transformed host cells (abstract, column 3, lines 44-56, and column 4, lines 50-67).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman Patent Examiner, Group 1633 November 5, 2001 DAVET. NGUYEN PRIMARY EXAMINER